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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,154	10/12/2001	Hugh S. West JR.	14000.11	3848

7590 06/27/2003

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[REDACTED] EXAMINER

RAMANA, ANURADHA

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

3732

DATE MAILED: 06/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/977,154	WEST, HUGH S.
Examiner	Art Unit	
Anu Ramana	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 October 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12 October 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2 and 3</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: providing an interference screw having a discontinuous taper and anchoring the tissue graft within a bone tunnel by installing the screw in the bone tunnel to interferingly engage the graft and the wall of the bone tunnel.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 11-13 and 17-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Rieser et al. (US 6,387,129).

Regarding claims 1-7, 11 and 17-21, Rieser et al. disclose an interference screw 20 for securing a graft in a bone tunnel with a threaded body having a proximal threaded section 26 with an angled back or face with an angle relative to its central axis of about 10° to about 80° so that it can be oriented flush with the outer surface of the bone; a distal threaded section 30 having an average diameter less than the average diameter of the proximal threaded section; and a recess 28 extending through the screw body sized and configured to receive at least a portion of a drive

shaft of a driver used to insert the screw into a bone tunnel wherein body 22 of screw 20 is tapered (col. 2, lines 41-47, col. 4, lines 4-18 and Figure 3).

Regarding claims 4-6 and 19-20, a transition section is an inherent feature of a tapered screw wherein the diameter varies from one end to another.

Regarding claim 12, the location of the proximal and distal portions of screw 20 is inherent to the location of the bone tunnel in which the screw is placed (col. 4, lines 35-49).

Regarding claim 13, Rieser et al. disclose that screw 20 is made of poly-l-lactic acid or titanium (col. 2, lines 48-57).

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Huebner (US 5,234,430).

Huebner discloses an orthopedic fixation screw 14 with a discontinuous taper for anchoring a bone or "tissue" graft in a bore or bone tunnel formed in a bone mass (Figure 1, col. 1, lines 52-59, col. 2, lines 20-47, col. 3, lines 10-42 and col. 4, lines 3-15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 9 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rieser et al.

Regarding claims 8 and 9, Rieser et al. disclose that interference screw 20 has an angled back or face with an angle relative to its central axis of about 10° to about 80°. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided screw 20 with a face having an angle relative to its central axis in a range of about 20° to 60° or 30° to about 40°, since it has been held that where the general conditions of a claim are

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disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claims 14 and 15, Rieser et al. disclose that tapered screw 20 has a diameter of about 9 to 10 mm (col. 4, lines 62-67 and col. 5, lines 1-2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided screw 20 with proximal and distal threaded sections having the claimed diameters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claim 16, although Rieser et al. disclose screw 20 as having a length of 10 to 20 mm, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided screw 20 with a length in a range of about 35 mm to 40 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rieser et al. in view of Huebner.

Regarding claim 10, Rieser et al. do not disclose that at least one of the proximal and the distal threaded section has a constant diameter.

Huebner teaches a fixation screw 14 with a threaded body portion or "proximal threaded section" 18 having a cylindrical root (constant diameter), a threaded tapered portion 20 having a root which tapers from the distal threaded portion 18 to the distal end or nose 16 of screw 14 for advancement of screw 14 in a bore 48 (col. 2, lines 20-46, col. 3, lines 10-42 and col. 4, lines 3-15).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided screw 20 of Rieser et al. with a proximal threaded section having a constant diameter and a threaded tapered portion between the proximal threaded section and the distal tip, as taught by Huebner for advancement of the Rieser et al.-Huebner screw in a bone tunnel.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

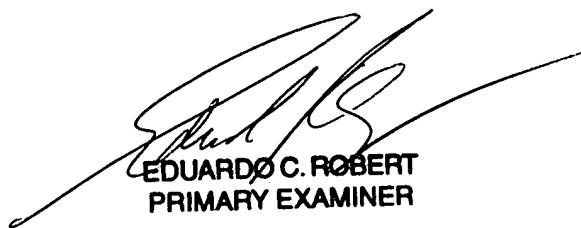
Applicant's attention is specifically directed to Siddiqui (US 6,306,140): Figure 1; col. 3, lines 59-67; and col. 4, lines 1-15.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR *Anuadha Ramana*
June 24, 2003



EDUARDO C. ROBERT
PRIMARY EXAMINER